CLAIMS

We claim:

1. (Currently amended) An extended release osmo microsealed formulation comprising:

an inner solid osmo-microsealed particulate phase being comprised of a therapeutically effective amount of venlafaxine Active or salt thereof and at least one osmogen/osmotic agent or osmo polymer, a diluent, a binder and a hydrophobic polymer membrane forming the core; and

an outer solid continuous phase being comprised of a hydrophilic water soluble and /or swellable polymer, compressed into tablets and optionally coated with a functional coat.

2. (Original) The formulation of claim 1, wherein the inner osmo microsealed particulate phase and the outer continuous phase is in a ratio within the range of 0.3:1 to 10:1, preferably from 0.5:1 to about 4:1.

3. (Currently amended) The formulation of claim 1, wherein the inner solid particulate phase is comprised of active drug or salt there of in an amount within the range from about 5% to 75%, preferably from about 7 % to 65 % by weight, ethyl cellulose and / or cellulose acetate in an amount within the range from 0.5 % to 65 % by weight, preferably from 2 % to 45 % by weight sodium chloride and / or mannitol in the range from 0.01 % to 25 % by weight, preferably from 0.05 % to 10 % by weight, Polyvinyl pyrolidone and / or Hydroxypropyl methylcellulose (low viscosity) in the range from 0.1 % to 10 % by weight, preferably from 0.5 % to 8 % by weight; and wherein the inner solid particulate phase is further comprised of microcrystalline cellulose and / or lactose in an amount within the range from about 0 % to 90 % by weight, preferably from 20 % to 80 % by weight, the above percentages being based on the weight of the inner solid particulate phase, wherein binding provided by diluents like lactose is sufficient, a specialty binder being excluded.

4. (Currently amended) The formulation of claim 1, wherein the inner solid particulate phase is further comprised of a hydrophobic polymer in an amount within the range from about 0.5% to 65% by wt. preferable from about 2% to 45% by wt. of the inner solid particulate phase.

5. (Original) The formulation of claim 4, wherein the hydrophobic polymer is used in the form of a non-aqueous solution, aqueous suspension, an aqueous emulsion or a water containing organic solvent solution.

6. (Currently amended) The formulation of claim 4, wherein the hydrophobic polymer is selected from a group consisting of: ethyl cellulose, methyl cellulose, amino methacrylate copolymer, methacrylic acid copolymers, methacrylic acid acrylic acid ethyl ester copolymer, methacrylic acid esters neutral copolymer, dimethyl aminoethyl methacrylate-methacrylic acid esters copolymer, Cellulose acetate, vinyl methyl ether/ maleic anhydride copolymers.

7. (Currently amended) The formulation of claim 1, wherein the inner solid particulate phase is further comprised of an osmogen in an amount within the range from about 0.01% to about 25% by wt. preferably from 0.05% to about 10% by wt. of the inner solid particulate phase.

8. (Currently amended) The formulation of claim 7, wherein the osmogens are selected from a group consisting of: organic and inorganic compounds such as salts, acids, bases, chelating agents, sodium chloride, lithium chloride, magnesium chloride, magnesium sulfate, lithium sulfate, potassium chloride, sodium sulfite, calcium bicarbonate, sodium sulfate, calcium sulfate, calcium lactate, d-mannitol, urea, tartaric acid, raffinose, sucrose, alpha-d-lactose monohydrate, glucose, sorbitol and the other similar or equivalent materials and combination thereof.

9. (Currently amended) The formulation of claim 1, wherein the inner solid particulate phase is further comprised of a binder in the range from about 0.1% to about 10% by wt. preferably from 0.5% to about 8% by wt of the inner solid particulate phase.

10. (Currently amended) The formulation of claim 9, wherein the binder is selected from a group consisting of: polyacryl amide, poly-N-vinyl amide, poly-N-vinyl-acetamide, polyvinyl pyrolidone, starch, lactose, modified corn starch, sugars, gum accacia, alginic acid, carboxymethylcellulose sodium, tragacanth, gelatin, liquid glucose, methylcellulose, pregelatinized starch, polyethylene glycol, guar gum, polysaccharide, bentonites, invert sugars, collagen, albumin, polypropylene glycol, polyoxyethylene-polypropylene copolymer, polyethylene ester, polyethylene sorbitan ester, polyethylene oxide, and hydroxypropyl methylcellulose and the other similar or equivalent materials or combination thereof.

11. (Original) The formulation of claim 10, wherein the viscosity of hydroxypropyl methylcellulose are of low viscosity preferably less than 10 Cps and more preferably 2 to 5 Cps.

12. (Currently amended) The formulation of claim 1, wherein the inner solid particulate phase is further comprised of a diluent in an amount within the range from about 0 to 90% by wt or preferably from about 20% to 80% by wt of the inner solid particulate phase.

13. (Original) The formulation of claim 12, wherein the diluent is an inert substance used as excipients to create the desired bulk flow properties and compression characteristic required in the preparation of tablets.

14. (Currently amended) The formulation of claim 12, wherein the diluent is selected from a groups consisting of: dibasic calcium phosphate, kaolin, lactose, sucrose, mannitol, microcrystalline

cellulose, powdered cellulose, precipitated calcium carbonate, sorbitol, and starch and the like materials.

15. (Original) The formulation of claim 1, wherein the inner solid particulate phase has a mean particle size within the range from about 0.01 micrometer to about 2mm, and preferably from about 50 micrometer to about 0.5 mm.

16. (Currently amended) The formulation of claim 1, wherein said outer solid continuous phase is further comprised of hydrophilic polymers in an amount within the range from about 3% to 60% by wt and preferably from about 10% to 55% by wt of the uncoated dosage form/tablet.

17. (Currently amended) The formulation of claim 16, wherein the hydrophilic polymer is selected from a groups consisting of: hydroxyethyl cellulose, hydroxypropyl cellulose, sodium alginate, carbomer (CarbopolTM), sodium carboxymethyl cellulose, xanthan gum, guar gum, locust bean gum, poly vinyl acetate, polyvinyl alcohol and hydroxypropyl methylcellulose.

18. (Currently amended) The formulation of claim 16, wherein said outer solid continuous phase is further comprised of one or more fillers or excipients in an amount within the range from about 1% to 70% by wt. and more preferably 10% to 40% by wt. of the uncoated dosage form/tablet.

19. (Currently amended) The formulation of claim 16, wherein said outer solid continuous phase is further comprised of a recommended level of glidants, lubricants, dry binders , anti adherents.

20. (Original) The formulation of claim 1, wherein the functional coat provided optionally is about 2% to 20% by wt. preferably from 2.5% to 10% by wt. of the uncoated tablet core.

21. (Currently amended) The formulation of claim 20, wherein the functional coating layer optionally provided over the outer solid continous phase containing particulates of inner solid phase

embedded therein, is further comprised of one ore more film formers such as methacrylic acid esters neutral polymer, ethyl cellulose, cellulose acetate, polyvinyl alcohol-maleic anhydride copolymers, beta-pinene polymers, glyceryl esters of wood resins and the like.

22. (Currently amended) The formulation of claim 20, further comprising:

a suitable colouring agent added in the coating.

23. (Currently amended) The formulation of claim 1, further comprising:

plastizers to modify the properties and chracteristic of polymers used in the coats of inner particulate phase and/or on the coat of compressed tablets.

24. (Currently amended) The formulation of claim 23, wherein the plastizers are selected from a group consisting of: low molecular wt polymers, low molecular weight polymers, oligomers, copolymers, oils, small organic molecules, low molecular weight polyols having aliphatic hydroxyls, ester-type plasticizers, glycol ethers, poly(propylene glycol), multi-block polymers, single block polymers, low molecular weight poly(ethylene glycol), citrate ester-type plasticizers, triacetin, propylene glycol and glycerin. Such plasticizers can also include ethylene glycol, 1,2-butylene glycol, 2,3-butylene glycol, styrene glycol, diethylene glycol, triethylene glycol, tetraethylene glycol and other poly(ethylene glycol) compounds, monopropylene glycol monoisopropyl ether, propylene glycol monoethyl ether, ethylene glycol monoethyl ether, diethylene glycol monoethyl ether, sorbitol lactate, ethyl lactate, butyl lactate, ethyl glycolate, dibutylsebacate, acetyltributylcitrate, triethyl citrate, acetyl triethyl citrate, tributyl citrate and allyl glycolate or combination thereof.

25. (Currently amended) The formulation of claim 24, wherein oils used are selected from a group consisting of: peanut oil, sesame oil, cottonseed oil, corn oil and olive oil; fatty acids, such as

oleic acid, stearic acid and isostearic acid; and fatty acid esters, such as ethyl oleate, isopropyl myristate, fatty acid glycerides, medium chain triglycerides and acetylated fatty acid glycerides.

26. (Currently amended) The formulation of claim 1, wherein the dosage form/tablet is further comprised of antiadherent, glidant, lubricant, opaquant, colorant, polishing agents, acidifying agent, alkalizing agent, antioxidant, buffering agent and surface active agent.

27. (Currently amended) The formulation of claim 26, wherein the antiadherent are selected from a group consisting of magnesium stearate, talc, calcium stearate, glyceryl behenate, Polyethylene glycols, hydrogenated vegetable oil, mineral oil, stearic acid and the like materials.

28. (Currently amended) The formulation of claim 26, wherein the glidant are selected from a group consisting of cornstarch, talc, calcium silicate, magnesium silicate, colloidal silicon dioxide, silicon hydrogel and the like materials.

29. (Currently amended) The formulation of claim 26, wherein the lubricant are selected from a group consisting of: calcium stearate, magnesium stearate, mineral oil, stearic acid, and zinc stearate and the like materials.

30. (Currently amended) The formulation of claim 26, wherein opaquant is used alone or in combination with colorant such as titanium dioxide and the like materials.

31. (Currently amended) The formulation of claim 26, wherein the colorant are selected from a group consisting of: FD&C Red No. 3, FD&C Red No. 20, FD&C Yellow No. 6, FD&C Blue No. 2, D&C Green No. 5, D&C Orange No. 5, D&C Red No. 8, caramel, and ferric oxide, red, other F.D. & C. dyes and natural coloring agents such as grape skin extract, beet red powder, beta-carotene, annato, carmine, turmeric, paprika and the like materials.

32. (Currently amended) The formulation of claim 26, wherein the polising agent are selected from a group consisting of camauba wax, white wax and the like materials.

33. (Currently amended) the formulation of claim 26, wherein the acidifying agent are selected from a group consisting of acetic acid, amino acid, citric acid, fumaric acid and other alpha hydroxy acids, such as hydrochloric acid, ascorbic acid, and nitric acid and the like materials.

34. (Currently amended) The formulation of claim 26, wherein the alkalizing agent are selected from a group consisting of: ammonia solution, ammonium carbonate, diethanolamine, monoethanolamine, potassium hydroxide, sodium borate, sodium carbonate, sodium bicarbonate, sodium hydroxide, triethanolamine, and trolamine and the like materials.

35. (Currently amended) The formulation of claim 26, wherein the antioxidants are selected from a group consisting of: ascorbic acid, ascorbyl palmitate, butylated hydroxyanisole, butylated hydroxytoluene, hypophophorous acid, monothioglycerol, propyl gallate, sodium ascorbate, sodium bisulfite, sodium formaldehyde sulfoxylate and sodium metabisulfite and the like materials.

36. (Currently amended) The formulation of claim 26, wherein the buffering agent are selected from a group consisting of: potassium metaphosphate, potassium phosphate, monobasic sodium acetate and sodium citrate anhydrous and dehydrate and the like materials.

37. (Currently amended) The formulation of claim 1, further comprising:

a dosage form/tablet having surfaces active agent that improve wetting of the tablet core or coating layers.

38. (Original) The formulation of claim 37, wherein the surface active agent are soaps and synthetic detergents.

39. (Currently amended) The formulaation of claim 38, wherein the soaps are further comprised of fatty acid alkali metal, ammonium, and triethanolamine salts.

40. (Original) The formulation of claim 38, wherein the detergents are cationic detergents, for example, dimethyl dialkyl ammonium halides, alkyl pyridinium halides, and alkylamine acetates; anionic detergents, for example, alkyl, aryl and olefin sulfonates, alkyl, olefin, ether and monoglyceride sulfates, and sulfosuccinates; nonionic detergents, for example, fatty amine oxides, fatty acid alkanolamides, and poly(oxyethylene)-block-poly(oxypropylene) copolymers; and amphoteric detergents, for example, alkyl .beta.-aminopropionates and 2-alkylimidazoline quaternary ammonium salts; and mixtures thereof.

41. (Currently amended) A process of preparing an extended release osmo-microsealed formulation comprising the following steps:

forming osmo microsealed inner solid particulate phase by granulation of venlafaxin active or salt thereof with one or more diluents to increase the bulk, binder to provide strength/hardness to the particulate one or more osmogen for generating osmatic pressure across the hydrpobic coating and hydrophobic polymer;

embedding the inner solid particulate phase in an outer solid continous phase being comprised of one or more hydrophilic polymers;

compressing the biphasic blend into tablet; and

coating the tablet optionally with a functional coat containing polymers.

42. (Currently amended) A process as claimed in claim 41, wherein the inner osmo microsealed particle coat is obtained by granulation of drug, diluent, binder and osmogen mixture

with the dispersion of the coating polymer forming a matrix of drug, diluent, osmogen and the polymer, the granules being re-granulated till the entire coat is applied if required.

43. (Currently amended) A process as claimed in claim 41, wherein the inner osmo microsealed particle coat is obtained by granulation of drug, diluent and binder with the solution of osmogen, said granulation being further continued with the dispersion of hydrophobic polymer, the granules being re-granulated till the entire coat is applied if required.

44. (Currently amended) A process as claimed in claim 41, wherein the inner osmo microsealed particle coat is obtained by granulation of drug, diluent and osmogen with the solution of binder, said granulation being further continued with the dispersion of hydrophobic polymer, the granules being re-granulated till the entire coat is applied if required.

45. (Currently amended) A process as claimed in claim 41, wherein the inner osmo microsealed particle coat is obtained by partial granulation of the drug, diluent and osmogen mixture with the dispersion of coating polymer forming a matrix of drug, diluent, osmogen and the polymer, said granules being further coated on a fluid bed processor with the remaining quantity of the hydrophobic polymer.

46. (Currently amended) A process as claimed in claim 41, wherein the inner osmo microsealed particle are obtained by granulation of the drug, osmogen and binder, said granules being coated on a fluid bed processor with the hydrophobic coating polymer.

47. (Currently amended) A process as claimed in claim 41, wherein the inner osmo microsealed particle are obtained by granulation of the drug, binder and diluent using a solution of osmogen, said granules being further coated on a fluid bed processor with the hydrophobic coating polymer

48. (Currently amended) A process as claimed in claim 41, wherein the inner osmo microsealed particle are obtained by extrusion-spheronization of wet blended mass of drug, binder, diluent and osmogen, mini spherules being obtained and coated on a fluid bed processor with the hydrophobic coating polymer.

49. (Canceled)

50. (Canceled)

51. (Canceled)

52. (Canceled)

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56. (Canceled)